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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/042,583	03/17/98	NI	J PF366

022195
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

HM22/0424

EXAMINER

KAUFMAN, C

ART UNIT	PAPER NUMBER
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1646

DATE MAILED:

04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/042,583

Applicant(s)

NI, ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 35-59, 61, 81-84, 86-100, 102-118, 120-149, 151-153, 155-166, 168, 169, 176-189, 191-202, 204-209, 211-222, 224-269, 272-286 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 152, 153, 155-166, 168, 169, 176-189, 191-202, 204, 257-269 and 272 is/are allowed.

6) ☒ Claim(s) 35, 36, 38, 39, 42, 49-57, 81, 82, 86-97, 100 and 102-115 is/are rejected.

7) ☒ Claim(s) 37, 40, 41, 43-48, 58, 59, 61, 83, 84, 98, 99, 116-118, 129-131, 134-138, 207-209, 211, 227-229, 245 and 246 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18, 21.

18) ☐ Interview Summary (PTO-413) Paper No(s). _____.

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other: _____.

6) Continuation of Claims that are rejected: 120-128, 132, 133, 139-149, 151, 205-206, 212-222, 224-226, 230-244, 247-256 and 273-286

DETAILED ACTION

The amendment filed 2/6/01 has been entered.

Response to Arguments

5 The rejection of claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims or in view of Applicant's arguments.

The rejection of claim 286 under 35 USC 112, first paragraph is withdrawn in view of the amendment to the claim.

10 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 242 is objected to because of the following informality: in line 7, "bind" should be --binds--. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

Claims 35, 36, 38, 39, 42, 49-57, 81, 82, 86-97, 100, 102-115, 120-128, 132, 133, 139-149, 151, 205-206, 212-222, 224-226, 230-241 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide that encodes the polypeptide of SEQ ID NO:2 or a specified fragment thereof or is 90% identical to a polynucleotide that encodes the polypeptide of SEQ ID NO:2 and binds TRAIL or is 90% identical to the polynucleotide of SEQ ID NO:1 or a specified fragment thereof, does not reasonably provide enablement for a polynucleotide that is not identical to SEQ ID NO:1 but most still encode a polypeptide or that is less than 100% identical to a polynucleotide encoding the polypeptide of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

25 The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level

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of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are two types of claims that are not enabled for the breadth of scope being claimed.

- 5 1) Claims are drawn to polynucleotides that are indirectly structurally related (*e.g.*, 90% identical to a nucleic acid that encodes a polypeptide....) to SEQ ID NO:1 or a specific fragment thereof or the corresponding degenerate coding sequence thereof. 2) Claims are also drawn to polynucleotides that are directly structurally related though not identical to the disclosed encoding nucleic acid of a DR5 polypeptide (*e.g.* a polynucleotide encoding a polypeptide 90% identical to SEQ ID NO:2 or a specified fragment thereof) and encode a polypeptide which has no functional requirement.

For the first type of claim, the issue is that the polynucleotide does not need to closely resemble the disclosed encoding polynucleotide. Therefore, polynucleotides that are neither useful as specific nucleic acid probes nor as encoding functional polypeptides are encompassed but not enabled by the specification or prior art. Such polynucleotides are those that are less than 100% identical to a nucleic acid that encodes the polypeptide of SEQ ID NO:2 or a specified polypeptide fragment, as well as polynucleotides that are less than 90% identical to SEQ ID NO:1 due to the structure phrased in the claims in terms of relationship to an encoding polynucleotide instead of the disclosed DR5 polynucleotide of SEQ ID NO:1. Degeneracy of the genetic code means that an encoding polynucleotide does not need to closely resemble the naturally occurring (*i.e.*, disclosed) encoding polynucleotide. If the claimed polynucleotide does not closely resemble the disclosed encoding polynucleotide, then one skilled in the art does not know how to use it as a specific probe. These types of claims would be enabled if the structural relatedness of the claimed polynucleotide was sufficiently close to that of SEQ ID NO:1 so that the skilled artisan could use it as a probe for specific detection of SEQ ID NO:1 without undue experimentation (see for example claims 186 or 152).

For the second type of claim, the issue is that the polynucleotide may have some resemblance to the disclosed encoding polynucleotide, for example being 90% identical to SEQ ID NO:1, but also have to encode a polypeptide (or fragment). See claim 35 for example. If the claimed polynucleotide does not have to encode a functional polypeptide, then one skilled in the

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art does not know how to use either the polynucleotide or the encoded polypeptide which has no specific function. The specification does not teach how to use such polynucleotides even though they are encompassed by the present claims. The structural diversity of the claimed polynucleotides gives great breadth. These types of claims would be enabled if the claimed polynucleotide encoded a polypeptide with sufficient structural relatedness to that of SEQ ID NO:2 with a function specific to the polypeptide of SEQ ID NO:2 (e.g., specifically binding TRAIL) so that the skilled artisan could use the encoded polypeptide without undue experimentation (see for example claim 137).

Claim Rejections - 35 USC § 102

Claims 225, 226, 230, 231, 234-240, 242-244, 247, 248, 251-255, 273-276 and 279-285 remain rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Accession No. AA223122 (V) for the reasons set forth in the previous Office action (paper #17) on pages 5-6.

Applicant argues that with the assumed proper reading frame of the GenBank nucleic acid, the resulting polypeptide would not meet the requirements of the rejected claims. The argument has been fully considered, but is not persuasive. The polynucleotide has a reading frame that would lead to encoding of amino acids as claimed, regardless of whether that reading frame was specified by the authors. The nucleotides of GenBank Accession No. AA223122 97% identical to the corresponding region of SEQ ID NO:1 of the instant application can encode a polypeptide that corresponds to amino acids -15 through 138 of SEQ ID NO:2 of the instant application.

Applicant argues that a single nucleotide insertion of the GenBank sequence leads to a fragment shift is not persuasive because the claims do not require 100% identity and therefore, a deletion at the site Applicant indicates is within the % percent identity within the limit of the claims. Because 100% identity to SEQ ID NO:1 or the specified fragment thereof is not required nor is the requirement of encoding a particular fragment of SEQ ID NO:2 (100% identity for the encoded fragment) in the claims, differences between the reference and disclosed sequences such as single nucleic acids differences that would change codons leading to amino acid substitutions or stop codons, does not affect anticipation of the claims. This is why the rejection has not been applied to claims requiring absolute identity, such as claim 227.

Claim Rejections - 35 USC § 103

Claims 225, 226, 230-244, 247-256 and 273-286 remain rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession No. AA223122 (V) and Chinnaiyan et al. (Science, 1996, cited by Applicants), Sibson et al. (WO 94/01548, N), and Bjorn et al. (V, Current Biol., 1992) in view of Adair et al. (O, WO 91/09967) for the reasons set forth in the previous Office action (paper #17) on pages 6-7.

Applicant argues that the prior art must have suggested that the claimed composition should be made (motivation for doing), that doing so would have a reasonable expectation of succession, and that all claim limitations must be taught or suggested. The argument has been fully considered, but is not persuasive. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992) [emphasis added by Examiner]. In this case, Sibson et al. in combination with the other references provides motivation to express polynucleotides which may only be partial sequences. There are only 3 possible reading frames. Applicants have not pointed out why one would not have a reasonable expectation of success in expressing the GenBank polynucleotide. It was routine at the time the invention was made to express partial sequences. One would have had a reasonable expectation of successful expression (i.e., translation) of the GenBank sequence.

Applicants argue that as discussed for the 35 USC 102 rejection, the GenBank polynucleotide cannot encode a contiguous polypeptide as required by the claims. The argument has been fully considered, but is not persuasive. The argument is addressed above.

Conclusion

Claims 37, 40, 41, 43-48, 58, 59, 61, 83, 84, 98, 99, 116-118, 129-131, 134-138, 207-209, 211, 227-229, 245 and 246 are objected to as depending on rejected claims.

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Claims 152, 153, 155-166, 168, 169, 176-189, 191-202, 204, 257-269 and 272 are allowable.

Any inquiry concerning this communication or earlier communications from the
5 examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791.
Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be
10 directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or
informal communications with the examiner should be directed to (703) 308-0294. NOTE: If
applicant *does* submit a paper by fax, the original signed copy should be retained by the
15 applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**
so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the
telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

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Patent Examiner, Art Unit 1646

April 18, 2001